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⑪ Publication number:

0 126 520
A2

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EUROPEAN PATENT APPLICATION

⑬ Application number: 84300875.6

⑮ Int. Cl.: A 61 F 1/00

⑭ Date of filing: 13.02.84

⑯ Priority: 16.02.83 GB 8304264

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⑲ Date of publication of application: 28.11.84
Bulletin 84/48

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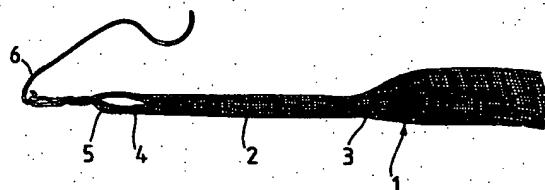
㉑ Designated Contracting States: AT BE CH DE FR GB IT
LI LU NL SE

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㉓ Prosthetic ligament and instruments for use in the surgical replacement of ligaments.

㉔ This invention relates to a new prosthetic ligament (1), and a set of surgical instruments for use in the surgical replacement of a ligament and in particular for inserting a prosthetic ligament into the body.

The ligament in accordance with the invention comprises an elongate foraminous flexible strip, the size and distribution of the perforations being substantially uniform along the length of the ligament.



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**PROSTHETIC LIGAMENT AND INSTRUMENTS FOR USE IN THE SURGICAL
REPLACEMENT OF LIGAMENTS**

This invention relates to a new prosthetic ligament and a set of surgical instruments for use in the surgical replacement of a ligament and in particular for inserting a prosthetic ligament into the body.

5 In the past damaged ligaments have been replaced by grafts from other tissues of the body. However, this is not satisfactory since extensive surgery is involved and the fixation of the replacement ligament is not always adequate. Also, solid tubes of polyethylene have been used
10 as ligaments but again the fixation of these ligaments was not satisfactory, and, further, the structure of the ligament was not suitable. Around three or four years ago carbon fibres were introduced as a possible ligament prosthesis. Holes are drilled into the bones to be joined by the
15 ligament and multifilament strands of carbon fibres are thread through these holes, the carbon fibres being long enough to allow the strands to be knotted to fix the fibres into position. The carbon fibre proves stronger than previous materials and growth of tissue is encouraged along
20 the length of the fibres. However, the holes which are required to be drilled in each bone are numerous and this involves large destruction of bone material which is not desirable. Further, control of the length of the ligament and its tension has proved very difficult, and anchoring
25 to the bone has not been accepted to any degree of consistency.

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One ligament which has been proposed in U S Patent number 4255820, comprises a foraminous tube which has perforations of different size and density along its length. The perforations in the central portion of the ligament which extends between the two bones are very small in order to prevent any tissue ingrowth in this area. An internal central core is inserted into this area to help ensure that no tissue ingrowth occurs.

According to this invention there is provided a prosthetic ligament for implantation between two bones, the ligament being elongate and flexible and including two ends, each end for fixation to a bone, with a central portion of ligament extending between said ends, said central portion comprising a foraminous polyester strip characterised in that the central portion includes perforations having an area of at least 0.01 cm^2 so that tissue ingrowth into the central portion is promoted.

In order to simplify the manufacturing process of the ligament it is preferred that the size and distribution of the perforations in the ligament is substantially uniform along the entire length of the ligament.

The ligament may be a perforated strip of material but is preferably a fabric with an open weave structure. Preferably the polyester is polyethylene terephthalate or a copolymer thereof, for instance, the material which is marketed under the trade mark "Terylene" in the U K and under the trade mark "Dacron" in U S A. The weave of the fabric may be knitted open net but is preferably mock leno or leno woven, in which the weft threads are locked with respect to the warp threads.

Preferably there are 10-40 perforations per square cm and more preferably 15-25 perforations per cm^2 .

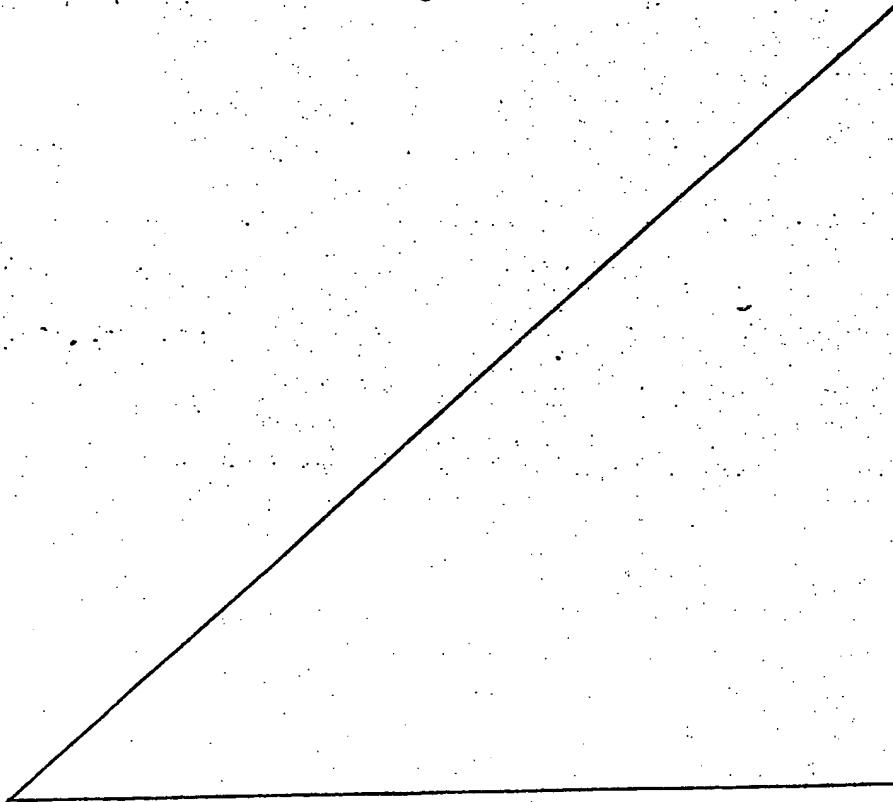
Each perforation is preferably in the range of 0.01 to 0.05 cm^2 and is more preferably in the range of 0.01 to 0.02 cm^2 .

Preferably such a ligament is fixed within the body by threading the prosthetic ligament through a bore in the

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two bones to be joined by the ligament. Each bore comprises
a reduced diameter portion which extends from the point at
which the original ligament was attached to the bone and
an enlarged diameter portion formed by removing a plug
5 of bone. The bone plugs are replaced into these enlarged
diameter portions when the ligament has been inserted thus
securing the ligament between the bone plug and the rest
of the bone. The perforations in the ligament which
extend through the length of the ligament promote growth
10 of the tissue. The perforations in the region of the bone
encourage bone growth which grows between the bone plug
and the rest of the bone thus securing and giving a good
fixation to the prosthetic ligament. The perforations in
the region between the two bones encourages tissue growth
15 along the length of the ligament which can



strengthen the ligament considerably.

The ligament may be formed from a length cut from an elongate strip which is inserted in the body and then trimmed once the ligament is fixed in place. Clearly 5 the perforations need only exist in the part of the ligament which remains in the body.

A particularly useful structure for the prosthetic ligament is for the ligament to be formed from a tube of open weave polyester. The tube includes a longitudinal 10 slit at each end of the ligament. One of the slits extends to one end edge of the ligament. At the other end of the ligament, at the end of that slit which is remote from the centre of the ligament is a closure which seals off the tube.

15 When the ligament is inserted in the bone, a bone plug is inserted in the slit adjacent the seal and the other end of the ligament is pulled. This means that the bone plug is forced between the shoulder between the enlarged portion and the reduced diameter portion of the 20 bore and the seal giving a good fixed location of the ligament. The other bone plug is then inserted through the slit at the other end of the ligament and forced against the shoulder in the other bone thus securing the ligament to both bones.

25 Preferably the ligament also includes means to pull the ligament through the two bores in the bones. Preferably this is in the form of a cord attached to one end of the ligament which may easily be threaded through the small bores.

30 Preferably the ligament is trimmed after the bone plugs have been inserted, the trimming removing the cord for threading the ligament through the bones and the sealed end of the slit.

35 Also in accordance with this invention there is provided a set of surgical instruments for use in the surgical replacement of an artificial ligament.

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According to this invention a clamp for locating the axis along the bore through which the ligament is to be threaded comprises two parallel limbs which are connected by two screw threaded members which extend perpendicularly of the limbs, one limb including a guide pin which extends perpendicular to the limb, the other limb including two guide pins parallel to this first guide pin and aligned with the guide pin and a cylindrical guide, to which they are attached, for receiving surgical instruments, the axis of the cylinder lying on the line of the first guide pin, the cylindrical guide being such that the edge of the cylinder lying between two limbs is tilted such that when the first guide pin is placed at the point where the original ligament was attached to the bone and the clamp is rotated until the angle of the tilt of the cylinder guide is parallel to the angle of the bone and the clamp is tightened, the axis extending from the centre of the cylindrical guide to the first guide pin is the required axis for the bore.

Preferably the handles used to tighten the screw threaded members are adjacent each other on the same side of the parallel limbs so that a surgeon only requires access to one side of the clamp.

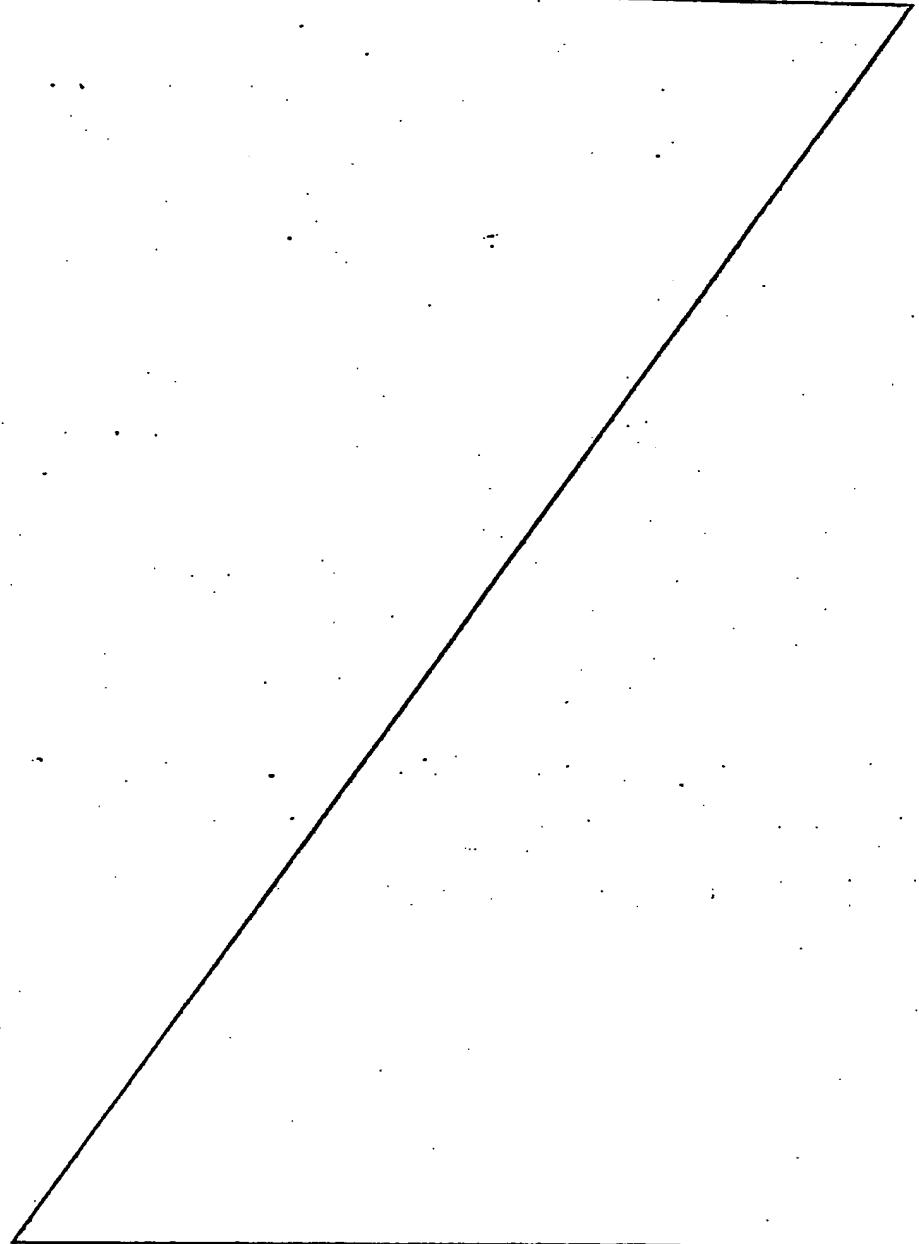
When the clamp has been placed on the bone, a reamer is inserted in the cylindrical guide and is used to remove an annulus of bone dust from the bone. This locates the plug of bone to be removed and the clamp can now be removed. Very occasionally the bone plug may be retained within the reamer. Preferably the reamer includes an opening through which a rod may be inserted to urge the plug out of the reamer.

According to this invention a bone plug extractor comprises a hollow cylindrical member of the same diameter as the annulus of bone dust removed from the bone and of a depth greater than that removed by the reamer, the cylinder including a cut out portion at the end inserted into the annulus in the bone, and including a flattened portion

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which does not enter the bone, the flattened portion forming a bearing surface to which is applied a short strong force to knock the annulus of bone to remove the bone plug from the rest of the bone.



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The bone plug extractor preferably includes a handle which may be gripped whilst the force is applied so that no bone damage occurs.

5 The bone plug may be removed from the plug extractor by inserting a rod into the cut out portion.

When the bone plug has been removed a cylindrical guide is placed into the cylinder in the bone, a drill bit is then placed within the cylindrical guide and a reduced diameter portion is then drilled from the base of the 10 cylinder to the other side of the bone at the point where the original ligament was attached to the bone.

This process is then repeated with the other bone to which the ligament is to be attached, the same instruments being used again.

15 Thus a set of tools according to this invention includes an above mentioned clamp, a reamer which cooperates with this clamp, a bone plug extractor of the same diameter as the annulus of the reamer, a rod which may be used with the bone plug extractor, and a cylindrical drill bit guide 20 of the same diameter as the reamer and bone plug extractor.

Preferably this ligament is used to replace the cruciate ligaments of the knee. It can also, in another form, for instance a flat strip, be used to replace the medial ligament of the knee.

25 A prosthetic ligament and a set of surgical instruments and a method of inserting the ligament into the body will now be described by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 is a perspective view of the prosthetic ligament;

30 Figure 2 is a perspective view of the clamp, reamer, drill bit guide;

Figure 3 is a perspective view of the bone plug extractor;

35 Figures 4 to 10 are schematic representations of the steps of the method of replacing an anterior cruciate ligament in the knee.

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An artificial ligament 1 comprises an elongate strip of open weave polyester. This fabric is Terylene and is a mock leno weave comprising a warp of 550 Decitex polyester yarn and a weft of twisted polyester yarn. The holes are 5 0.1×0.5 cm. There are 14 to 15 holes across the width of the strip, and 20 holes per cm^2 .

The ligament is in the form of a tube 2 which has a slit 3 at one open end of the ligament 1 which extends to the open end edge of the ligament and a slit 4 at the 10 other closed end of the ligament. The end of the slit 4 remote from the centre of the tube 2 is sealed by a row or more of stitching 5 or a comparable method, to form a pouch. In order to illustrate the slit 4, the ligament 1 has been shown in Figure 1 with a dark coloured tubular 15 insert. This means that the pouch-like structure is not clearly illustrated. A cord 6 is attached to the end of the ligament to pull the ligament through the bores in the bone.

A set of surgical instruments for use in the implantation of the ligament comprises a clamp 7, a reamer 8, a 20 bone plug extractor 9, and a drill bit guide 12.

The clamp 7 comprises two parallel limbs 13, 14 connected by two perpendicular screw threaded members 15 and 16. One limb includes a first guide pin 17 standing 25 perpendicularly of the limb. The other limb 14 includes two guide pins 18 which are parallel to the guide pin 17 and extend towards the guide pin 17. Also connected to limb 14 is a cylindrical guide 19 which has a surface 20 between the two limbs which is tilted, the two guide pins are screwed into the cylindrical guide 19.

The reamer 8 passes through the cylindrical guide 19 and has sharp cutting edges 21, which are milled along its surface and form sharp teeth at the rim of the reamer, and a handle 22 which may be used to oscillate the cutting edges 21 to remove the bone dust.

The bone plug extractor 9 comprises a cylindrical portion 23 which includes a cut-out portion 24.

The bone plug extractor 9 has a flattened portion 25

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on its handle. The diameter of the cylindrical portion 23 is the same as the reamer.

5 The drill bit guide 12 is placed in the cylindrical hole created in the bone and is used as a guide for the drill bit to drill out the reduced diameter portion of the bore.

10 The anterior cruciate ligament in the knee is connected to the femur 26 and the tibia 27. As shown in Figure 4, the clamp 7 is placed around the femur 26 with the first 15 guide pin 17 placed at the point of attachment 28 where the original ligament was attached to the femur 26. The clamp is then rotated until the sloping edge 20 of the cylindrical guide 19 is aligned to the slope of the bone 26. The clamp 7 is then tightened up locating the axis 15 of the bore.

20 As shown in Figure 5 the reamer 8 is then placed within the cylindrical guide 20 and the handle 22 is oscillated to remove an annulus of bone dust (Figure 6). The reamer is then removed from the bone. In the infrequent possibility 25 that the bone plug is removed with the reamer, a rod is inserted into the reamer to remove the bone plug.

25 As shown in Figure 7 the bone plug extractor 9 is then placed in the annulus defined in the femur 26. A swift force is applied to the flattened surface 25 to remove the bone plug from the bone, whilst the bone plug extractor 9 is gripped firmly. The bone plug may be removed from the bone 30 plug extractor 9 by inserting a rod into opening 24.

The drill bit guide 12 is then placed in the cylindrical hole left in the femur 26 and a drill bit is then placed 35 within the guide 12 to drill out the reduced diameter portion 28 of the bore 29 now formed through the femur 26.

This procedure is then repeated in the tibia forming a bore in the tibia. The ligament 1 is then threaded through the two bores 29 using the cord 6. The bone plug 35 from the tibia 27 is then placed within the slit 4 in the ligament.

The other end of the ligament 1 is then pulled forcing

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the bone plug against the shoulder formed between the enlarged portion and the reduced diameter portion 28 by the sealed end 5.

5 The bone plug from the femur 26 is then forced into the opening 3, aided by a push rod. Thus the ligament 1 is secured to both the femur and tibia.

10 Subsequently the anchorage will be strengthened as a result of the bone growth between the bone plug and the rest of the bone. Also tissue growth is encouraged along the length of ligament between the bones thus strengthening the ligament.

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CLAIMS:

1. A prosthetic ligament for implantation between two bones, the ligament being elongate and flexible and including two ends, each end for fixation to a bone, with a central portion of ligament extending between said ends,
5 said central portion comprising a foraminous polyester strip characterised in that the central portion includes perforations having an area of at least 0.01 cm^2 so that tissue ingrowth into the central portion is promoted.
- 10 2. A prosthetic ligament according to claim 1, further characterised in that the entire ligament is foraminous and has perforations the size and distribution of which are substantially uniform along the length of the ligament.
- 15 3. A prosthetic ligament according to claim 1, further characterised in that the ligament comprises a polyester fabric with an open weave structure.
4. A prosthetic ligament according to claim 3, further characterised in that the polyester is polyethylene terephthalate or a copolymer thereof.
- 20 5. A prosthetic ligament according to any one of the claims 2 to 4, further characterised in that the weave of the fabric is mock leno or leno woven in which the weft threads are locked with respect to the warp threads.
6. A prosthetic ligament according to any one of the preceding claims, further characterised in that the
25 distribution of the perforations is in the range 10 to 40 perforations/ cm^2 .
7. A prosthetic ligament according to claim 6, further characterised in that the distribution of the perforations is in the range 15 to 25 perforations/ cm^2 .
- 30 8. A prosthetic ligament according to any one of the preceding claims, further characterised in that the size of the perforations is in the range 0.01 to 0.05 cm^2 .
9. A prosthetic ligament according to claim 8, further characterised in that the size of the perforations is in
35 the range of 0.01 to 0.02 cm^2 .
10. A prosthetic ligament according to any one of the

preceding claims, further characterised in that the ligament (1) is tubular, the tube including no core.

11. A prosthetic ligament according to claim 10, further characterised in that the tube (2) has a first open end and
5 a second closed end (5) and that a first longitudinal slit (3) extends from the first end to a point close to but spaced from the first end, and a second longitudinal slit (4) is situated adjacent the second closed end.

12. A prosthetic ligament according to claim 11, further
10 characterised in that it includes means to pull the ligament.

13. A prosthetic ligament according to claim 12, further characterised in that the means comprises a cord attached to one end of the ligament.

14. A bone plug extractor for use in the surgical replacement of a ligament comprising a hollow cylindrical portion (23) with one end open, the other end coupled to a handle portion including a flattened bearing surface (25).

15. A bone plug extractor according to claim 14, in which the cylindrical portion (23) includes a slot (24) extending
10 to the open end to facilitate removal of a bone plug from the bone plug extractor (9).

16. A bone plug extractor according to claim 14 or 15, in which the handle portion includes a gripping area to allow the handle to be gripped while force is applied to the
25 flattened surface (25).

17. A set of tools for use in the surgical replacement of prosthetic ligaments comprising a clamp (7) for locating the axis along which a bore is required for fixation of a ligament, a reamer (18) cooperable with the clamp (7) for
30 removing an annulus of bone dust, a bone plug extractor (9) according to any one of claims 14 to 16, of the same diameter as the reamer (8), and a cylindrical drill bit guide (12) of the same diameter as the reamer and bone plug extractor.

18. A set of tools according to claim 17, also including
35 a rod for removing a bone plug from the bone plug extractor.

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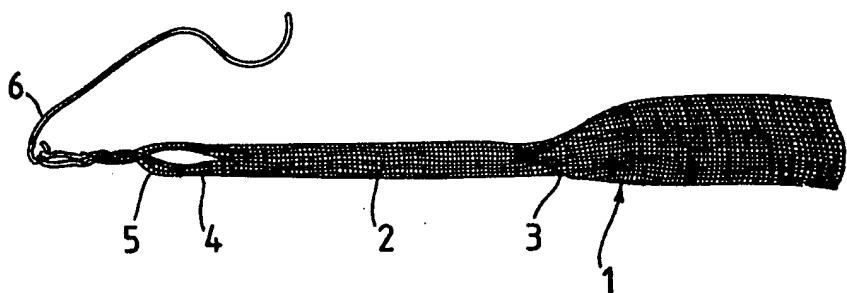


Fig.1.

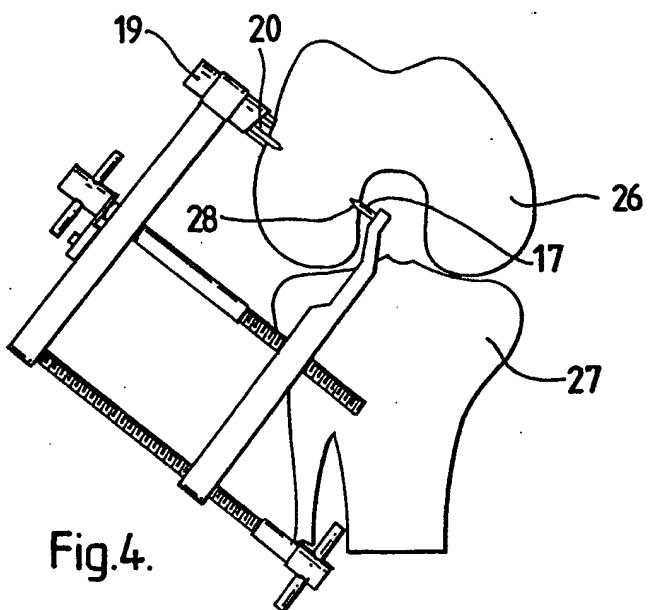
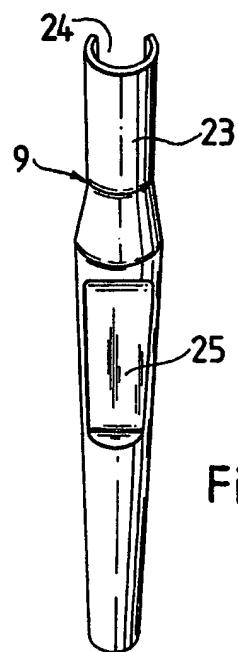
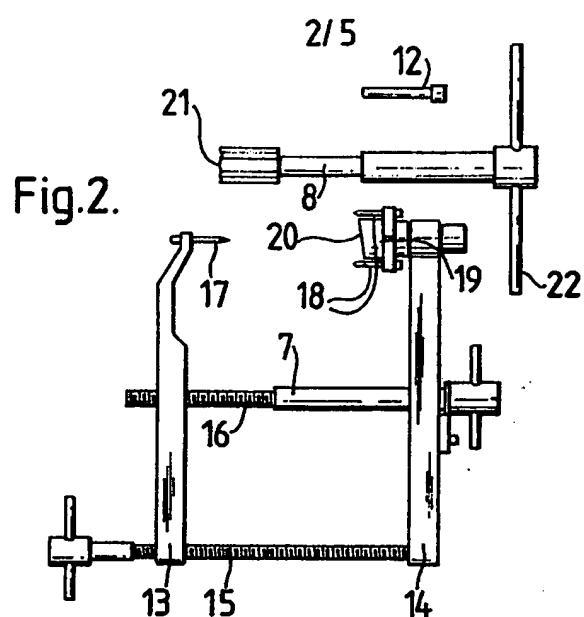
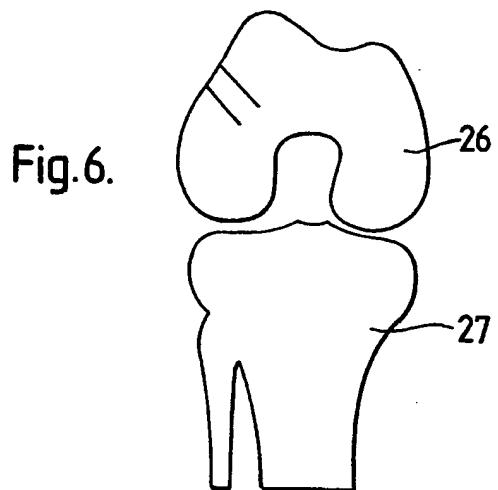
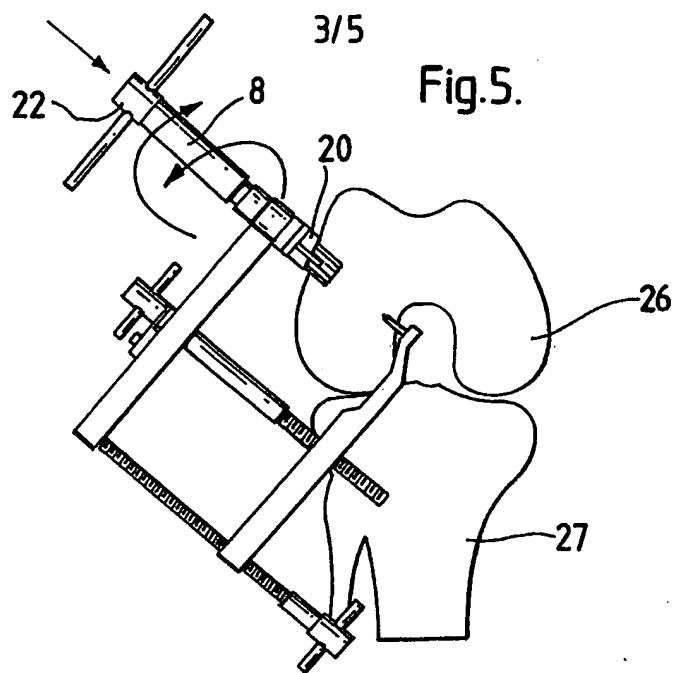


Fig.4.

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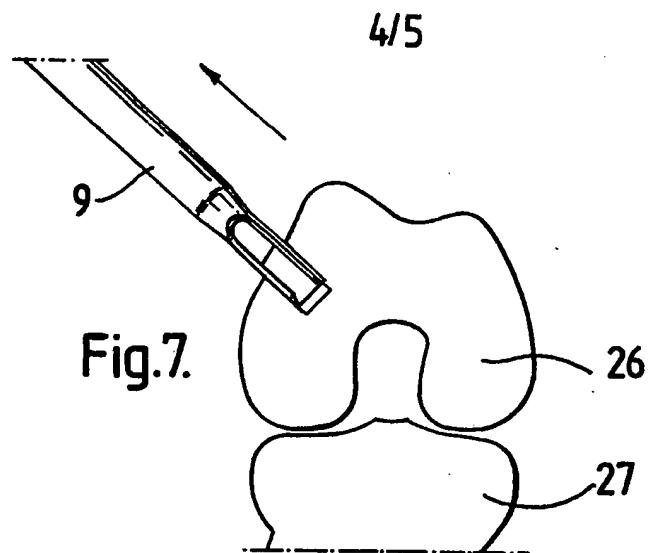


Fig.7.

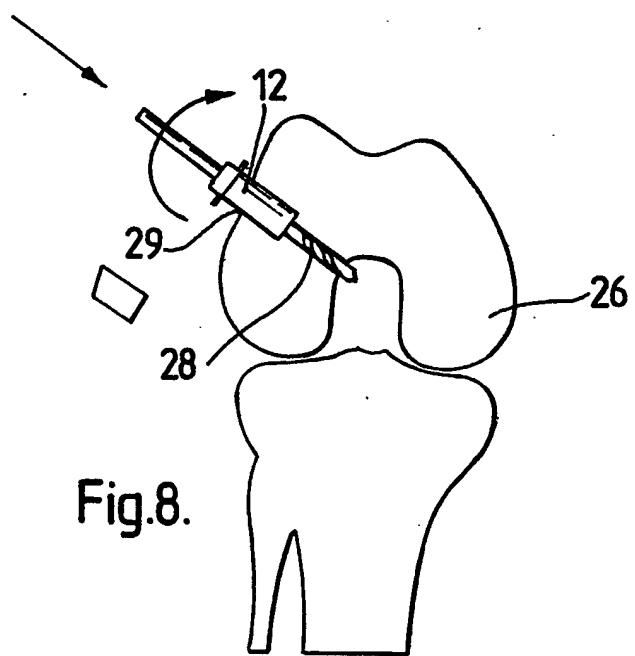


Fig.8.

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